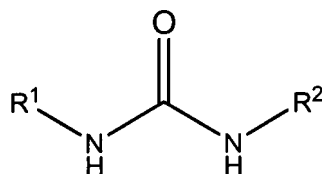


AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) A pharmaceutical formulation comprising a pharmaceutically accepted excipient and a therapeutically effective amount of a compound represented by Formula I:

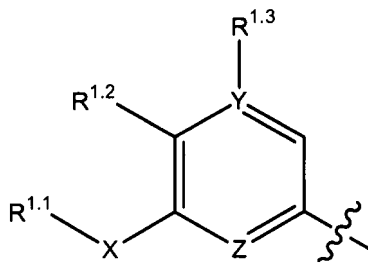


Formula I

wherein:

~~R¹ is optionally substituted aryl or optionally substituted heteroaryl;~~

R¹ is :



wherein:

X is -O-, -O-(optionally substituted lower alkylene)-, -(optionally substituted lower alkylene)-O-, -S-, -S-(optionally substituted lower alkylene)-, -(optionally substituted lower alkylene)-S-, -SO₂-, -SO₂-(optionally substituted lower alkylene)-, or -(optionally substituted lower alkylene)-SO₂-;

Y and Z are independently -C= or -N=, provided that both Y and Z are -C= or only one of Y or Z is -N=;

R^{1.1} is optionally substituted aryl, optionally substituted heteroaryl or optionally substituted heterocyclyl;

R^{1.2} is hydrogen, halo or optionally substituted heteroaryl; and

R^{1.3} is hydrogen, halo, optionally substituted heteroaryl or nitro; and

R² is optionally substituted aryl, optionally substituted aralkyl; optionally substituted cycloalkyl, optionally substituted heteroaryl, optionally substituted heteroaralkyl or optionally substituted heterocyclyl,

or a single stereoisomer, mixture of stereoisomers, or a pharmaceutically acceptable salt thereof. ~~, solvate, or a solvate of a pharmaceutically acceptable salt thereof.~~

2. (Cancelled)

3. (Currently amended) The ~~compound~~ formulation of Claim 1 [[2]] having one or more of the following:

X is -O-;

Y and Z are -C=;

R^{1.1} is tetrahydrofuranyl, tetrahydropyranyl, optionally substituted pyrrolidinyl, optionally substituted 3-oxo-tetrahydro-pyrrolo[1,2-c]oxazol-6-yl, optionally substituted morpholinyl, optionally substituted piperidinyl, optionally substituted pyridinyl or optionally substituted phenyl;

R^{1.2} is hydrogen or fluoro; and

R^{1.3} is pyridinyl or fluoro.

4. (Currently amended) The ~~compound~~ formulation of Claim 3 where:

~~Y and Z are -C=;~~

R^{1.1} is tetrahydrofuranyl, tetrahydropyranyl, substituted-pyrrolidinyl, 3-oxo-tetrahydro-pyrrolo[1,2-c]oxazol-6-yl, substituted-piperidinyl, pyridinyl or hydroxy-lower alkyl-phenyl;

R^{1.2} is hydrogen; and

R^{1,3} is fluoro.

5. (Cancelled)

6. (Currently Amended) The ~~compound~~ formulation of Claim 1 ~~[[2]]~~ where R^{1,1} is 1-acyl-pyrrolidin-3-yl, 1-alkoxycarbonyl-pyrrolidin-3-yl, 1-amidino-pyrrolidin-3-yl, 1-sulfonyl-pyrrolidin-3-yl, 3-oxo-tetrahydro-pyrrolo[1,2-c]oxazol-6-yl, 1-acyl-piperidin-3-yl, 1-alkoxycarbonyl-piperidin-3-yl, 1-amidino-piperidin-3-yl or 1-sulfonyl-piperidin-3-yl, optionally having an additional lower alkoxy or lower alkoxyalkyl ring substituent.

7. (Currently amended) The ~~compound~~ formulation of Claim 3 where R^{1,1} is 1-acyl-pyrrolidin-3-yl, 1-alkoxycarbonyl-pyrrolidin-3-yl, 1-amidino-pyrrolidin-3-yl, 1-sulfonyl-pyrrolidin-3-yl, 3-oxo-tetrahydro-pyrrolo[1,2-c]oxazol-6-yl, 1-acyl-piperidin-3-yl, 1-alkoxycarbonyl-piperidin-3-yl, 1-amidino-piperidin-3-yl or 1-sulfonyl-piperidin-3-yl, optionally having an additional lower alkoxy or lower alkoxyalkyl ring substituent.

8. (Currently amended) The ~~compound~~ formulation of Claim 4 where R^{1,1} is 1-acyl-pyrrolidin-3-yl, 1-alkoxycarbonyl-pyrrolidin-3-yl, 1-amidino-pyrrolidin-3-yl, 1-sulfonyl-pyrrolidin-3-yl, 3-oxo-tetrahydro-pyrrolo[1,2-c]oxazol-6-yl, 1-acyl-piperidin-3-yl, 1-alkoxycarbonyl-piperidin-3-yl, 1-amidino-piperidin-3-yl or 1-sulfonyl-piperidin-3-yl, optionally having an additional lower alkoxy or lower alkoxyalkyl ring substituent.

9. (Cancelled)

10. (Currently amended) The ~~compound~~ formulation of Claim 4 ~~[[5]]~~ where R^{1,1} is 1-acetyl-piperidin-3-yl, 1-methoxyacetyl-piperidin-3-yl, 1-(azetidine-1-carbonyl)-piperidin-3-yl, 1-methoxycarbonyl-piperidin-3-yl, 1-ethoxycarbonyl-piperidin-3-yl, 1-dimethylaminocarbonyl-piperidin-3-yl, 1-methanesulfonyl-piperidin-3-yl, 1-(ethane-2-sulfonyl)-piperidin-3-yl, 1-(propane-2-sulfonyl)-piperidin-3-yl, 1-(azetidin-1-yl-sulfonyl)-piperidin-3-yl, 1-dimethylaminosulfonyl-piperidin-3-yl, 1-(N¹-azetidin-1-yl-N²-cyano-

amidino)-piperidin-3-yl, 1-(*N*²-cyano-*N*¹,*N*¹-dimethylamidino)-piperidine-3-yl, 1-acetyl-pyrrolidin-3-yl, 1-methoxyacetyl-pyrrolidin-3-yl, 1-(azetidine-1-carbonyl)-pyrrolidin-3-yl, 1-methoxycarbonyl-pyrrolidin-3-yl, 1-methoxycarbonyl-2-methoxymethyl-pyrrolidin-4-yl, 1-methanesulfonyl-pyrrolidin-3-yl, 1-(ethane-2-sulfonyl)-pyrrolidin-3-yl, 1-(ethane-2-sulfonyl)-4-methoxy-pyrrolidin-3-yl, 1-(ethane-2-sulfonyl)-5-methoxymethyl-pyrrolidin-3-yl, 1-(propane-2-sulfonyl)-pyrrolidin-3-yl, 1-(azetidin-1-yl-sulfonyl)-pyrrolidin-3-yl, 1-dimethylaminosulfonyl-pyrrolidin-3-yl, 1-dimethylaminosulfonyl-2-methoxymethyl-pyrrolidin-4-yl, 1-(*N*¹-azetidin-1-yl-*N*²-cyano-amidino)-pyrrolidin-3-yl, 1-(*N*²-cyano-*N*¹,*N*¹-dimethylamidino)-pyrrolidin-3-yl, or 3-oxo-tetrahydro-pyrrolo[1,2-*c*]oxazol-6-yl.

11. (Currently amended) The ~~compound~~ formulation of Claim 10 where R^{1.1} is 1-acyl-pyrrolidin-3-yl, 1-sulfonyl-pyrrolidin-3-yl, 3-oxo-tetrahydro-pyrrolo[1,2-*c*]oxazol-6-yl, 1-alkoxycarbonyl-piperidin-3-yl or 1-sulfonyl-piperidin-3-yl.

12. (Currently amended) The ~~compound~~ formulation of Claim 11 where R^{1.1} is 1-methoxycarbonyl-2-methoxymethyl-pyrrolidin-4-yl, 1-(ethane-2-sulfonyl)-pyrrolidin-3-yl, 1-(ethane-2-sulfonyl)-5-methoxymethyl-pyrrolidin-3-yl, 1-dimethylaminosulfonyl-pyrrolidin-3-yl, 1-dimethylaminosulfonyl-2-methoxymethyl-pyrrolidin-4-yl, 3-oxo-tetrahydro-pyrrolo[1,2-*c*]oxazol-6-yl, 1-methoxycarbonyl-piperidin-3-yl, 1-methanesulfonyl-piperidin-3-yl, or 1-(ethane-2-sulfonyl)-piperidin-3-yl.

13. (Currently amended) The ~~compound~~ formulation of Claim 1 where R² is optionally substituted aryl or optionally substituted heteroaryl.

14. (Currently amended) The ~~compound~~ formulation of Claim 13 where R² is optionally substituted phenyl, optionally substituted naphthyl, optionally substituted pyrrolyl, optionally substituted, thiazolyl, optionally substituted isooxazolyl, optionally substituted pyrazolyl, optionally substituted pyridinyl, optionally substituted pyrazinyl, optionally substituted pyrimidinyl, or optionally substituted pyridazinyl.

15. (Currently amended) The ~~compound~~ formulation of Claim 13 where R² has one or two optional substituents selected from: acetyl, lower alkyl, lower alkoxy, lower alkoxyalkyl, lower alkoxy carbonyl, hydroxy lower alkyl, alkoxy lower alkyl, carboxy, halo and trifluoromethyl.

16. (Currently amended) The ~~compound~~ formulation of Claim 15 where R² is isooxazol-3-yl, 5-methyl-isooxazol-3-yl, isooxazol-5-yl, pyrazol-3-yl, pyrazinyl, substituted phenyl or optionally substituted pyridinyl.

17. (Currently amended) The ~~compound~~ formulation of Claim 16 where R² is:
phenyl having one or two substituents selected from: lower alkyl, lower alkoxy, halo, hydroxy and hydroxy lower alkyl; or
pyridin-2-yl, pyridin-3-yl or pyridin-4-yl optionally having a substituent selected from: acetyl, lower alkyl, lower alkoxy, lower alkoxyalkyl, lower alkoxy carbonyl, carboxy and trifluoromethyl.

18. (Currently amended) The ~~compound~~ formulation of Claim 17 where R² is optionally-*p*-substituted pyridin-3-yl.

19. (Currently amended) The ~~compound~~ formulation of Claim 18 where R² is pyridin-3-yl optionally *p*-substituted with a member of the group: acetyl, methyl, ethyl, methoxy, methoxymethyl, hydroxy, hydroxymethyl and hydroxyethyl.

20. (Currently amended) The ~~compound~~ formulation of Claim 19 where R² is pyridin-3-yl or 6-methyl-pyridin-3-yl.

21. (Currently amended) The ~~compound~~ formulation of Claim 1 where R² is optionally substituted aralkyl, optionally substituted cycloalkyl, optionally substituted heteroaralkyl or optionally substituted heterocyclyl.

22. (Currently amended) The ~~compound~~ formulation of Claim 21 where R² is represented by the formula –W-R^{2.1} where:

W is C₁ to C₃ straight or branched-chain alkylene; and

R^{2.1} is tetrahydrofuranyl, tetrahydropyranyl, optionally substituted pyrrolidinyl, optionally substituted morpholinyl, optionally substituted piperidinyl, optionally substituted pyridinyl or optionally substituted phenyl.

23. (Currently amended) The ~~compound~~ formulation of Claim 22 where:

W is methylene; and

R^{2.1} is tetrahydrofuran-2-yl, tetrahydrofuran-3-yl, N-acyl-pyrrolidin-2-yl, N-acyl-morpholin-3-yl, N-acyl-piperidin-3-yl, N-acyl-piperidin-4-yl, pyridin-3-yl, pyridin-4-yl, optionally substituted piperidinyl *p*-methoxy-phenyl or *p*-fluoro-phenyl.

24. (Currently amended) The ~~compound~~ formulation of Claim 21 where R² is tetrahydrofuran-2-yl, tetrahydrofuran-3-yl, N-acyl-pyrrolidin-2-yl, N-acyl-morpholin-3-yl, N-acyl-piperidin-3-yl, N-acyl-piperidin-4-yl or cyclohexyl.

25. (Currently amended) [[A]] The pharmaceutical formulation of claim 1 wherein the compound is selected from

1-[3-(1-Acetyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-(6-methoxy-pyridin-3-yl)-urea;

1-[3-(1-Acetyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-pyridin-3-yl-urea;

1-[3-Fluoro-5-(1-methanesulfonyl-piperidin-3-yloxy)-phenyl]-3-pyridin-3-yl-urea;

1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-carboxylic acid methyl ester;

(R)-1-[3-(1-Acetyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-(6-methoxy-pyridin-3-yl)-urea;

(R)-1-[3-(1-Acetyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-pyridin-3-yl-urea;

(R)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-carboxylic acid methyl ester;

(R)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-carboxylic acid dimethylamide;

(R)-1-[3-Fluoro-5-(1-methanesulfonyl-piperidin-3-yloxy)-phenyl]-3-pyridin-3-yl-urea;

(R)-1-[3-(1-Acetyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-(6-methyl-pyridin-3-yl)-urea;

(R)-1-[3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy]-piperidine-1-carboxylic acid methyl ester;

(R)-1-[3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy]-piperidine-1-carboxylic acid dimethylamide;

(R)-1-[3-Fluoro-5-(1-methanesulfonyl-piperidin-3-yloxy)-phenyl]-3-(6-methyl-pyridin-3-yl)-urea;

(R)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-carboxylic acid ethyl ester;

(R)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-sulfonic acid dimethylamide;

(R)-1-[3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy]-piperidine-1-sulfonic acid dimethylamide;

(R)-1-[3-Fluoro-5-[1-(propane-2-sulfonyl)-piperidin-3-yloxy]-phenyl]-3-pyridin-3-yl-urea;

(R)-1-[3-Fluoro-5-[1-(propane-2-sulfonyl)-piperidin-3-yloxy]-phenyl]-3-(6-methyl-pyridin-3-yl)-urea;

(R)-1-[3-(1-Ethanesulfonyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-pyridin-3-yl-urea;

(R)-1-[3-(1-Ethanesulfonyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-(6-methyl-pyridin-3-yl)-urea;

(S)-3-[3-Fluoro-5-(pyridin-3-yl-ureido)-phenoxy]-piperidine-1-N,N-dimethyl-N-cyano-carboxamidine;

(S)-3-[3-Fluoro-5-(2-methyl-pyridin-5-yl-ureido)-phenoxy]-piperidine-1-N,N-dimethyl-N-cyano-carboxamidine;

(S)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-sulfonic acid dimethylamide;

(S)-1-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-piperidine-1-sulfonic acid dimethylamide;

(S)-1-[3-(1-Ethanesulfonyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-pyridin-3-yl-urea;

(S)-1-{3-Fluoro-5-[1-(propane-2-sulfonyl)-piperidin-3-yloxy]-phenyl}-3-pyridin-3-yl-urea;

(S)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-carboxylic acid methyl ester;

(S)-1-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-piperidine-1-carboxylic acid ethyl ester;

(S)-1-[3-(1-Ethanesulfonyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-(6-methyl-pyridin-3-yl)-urea;

(S)-1-{3-Fluoro-5-[1-(propane-2-sulfonyl)-piperidin-3-yloxy]-phenyl}-3-(6-methyl-pyridin-3-yl)-urea;

(S)-1-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-piperidine-1-carboxylic acid methyl ester;

(S)-3-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-piperidine-1-carboxylic acid methyl ester;

(S)-1-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-piperidine-1-carboxylic acid ethyl ester; and

(S)-1-[3-Fluoro-5-(1-methanesulfonyl-piperidin-3-yloxy)-phenyl]-3-pyridin-3-yl-urea;

~~or a single stereoisomer, mixture of stereoisomers, or a pharmaceutically acceptable salt, solvate, or a solvate of a pharmaceutically acceptable salt thereof.~~

26. (Currently amended) [[A]] The pharmaceutical formulation of claim 1 wherein the compound is selected from:

(S)-3-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-pyrrolidine-1-sulfonic acid dimethylamide;

(R)-3-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-pyrrolidine-1-sulfonic acid dimethylamide;

(S)-3-[3-Fluoro-5-(2-methyl-pyridin-5-yl-ureido)-phenoxy]-pyrrolidine-1-N,N-dimethyl-N-cyano-carboxamidine;

(R)-3-[3-Fluoro-5-(2-methyl-pyridin-5-yl-ureido)-phenoxy]-pyrrolidine-1-N,N-dimethyl-N-cyano-carboxamidine;

(S)-3-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-pyrrolidine-1-sulfonic acid dimethylamide;

(S)-3-[3-Fluoro-5-(pyridin-2-yl-ureido)-phenoxy]-pyrrolidine-1-N,N-dimethyl-N-cyano-carboxamidine;

(R)-3-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-pyrrolidine-1-sulfonic acid dimethylamide;

(R)-3-[3-Fluoro-5-(pyridin-2-yl-ureido)-phenoxy]-pyrrolidine-1-N,N-dimethyl-N-cyano-carboxamidine;

(S)-3-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-pyrrolidine-1-carboxylic acid methyl ester;

(S)-3-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-pyrrolidine-1-carboxylic acid methyl ester;

(R)-3-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-pyrrolidine-1-carboxylic acid methyl ester;

(R)-3-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-pyrrolidine-1-carboxylic acid methyl ester;

(S)-1-{3-Fluoro-5-[1-(propane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-pyridin-3-yl-urea;

(S)-1-{3-Fluoro-5-[1-(propane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-(6-methyl-pyridin-3-yl)-urea;

(S)-1-{3-Fluoro-5-[1-(ethane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-pyridin-3-yl-urea;

(S)-1-{3-Fluoro-5-[1-(ethane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-(6-methyl-pyridin-3-yl)-urea;

(R)-1-{3-Fluoro-5-[1-(ethane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-pyridin-3-yl-urea;

(S)-1-{3-Fluoro-5-[1-(methane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-(6-methylpyridin-3-yl)-urea;

(R)-1-{3-Fluoro-5-[1-(ethane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-(6-methylpyridin-3-yl)-urea;

(R)-1-{3-Fluoro-5-[1-(propane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-(6-methylpyridin-3-yl)-urea;

(S)-4-{3-Fluoro-5-[3-(6-methylpyridin-3-yl)-ureido]-phenoxy}-[(S)-2-methoxymethyl]-pyrrolidine-1-sulfonic acid dimethylamide;

(S)-4-{3-Fluoro-5-[3-(6-methylpyridin-3-yl)-ureido]-phenoxy}-[(S)-2-methoxymethyl]-pyrrolidine-1-carboxylic acid methyl ester;

(R)-1-{3-(1-Ethanesulfonyl-[(R)-4-methoxy]-pyrrolidin-3-yloxy)-5-fluoro-phenyl}-3-(6-methylpyridin-3-yl)-urea;

(R)-1-{3-(1-Ethanesulfonyl-[(S)-5-methoxymethyl]-pyrrolidin-3-yloxy)-5-fluoro-phenyl}-3-pyridin-3-yl-urea;

(R)-1-{3-(1-Ethanesulfonyl-[(S)-5-methoxymethyl]-pyrrolidin-3-yloxy)-5-fluoro-phenyl}-3-(6-methylpyridin-3-yl)-urea;

1-[3-Fluoro-5-(R)-(3-oxo-(S)-tetrahydro-pyrrolo[1,2-c]oxazol-6-yloxy)-phenyl]-3-pyridin-3-yl-urea; and

1-[3-Fluoro-5-(R)-(3-oxo-(S)-tetrahydro-pyrrolo[1,2-c]oxazol-6-yloxy)-phenyl]-3-(6-methylpyridin-3-yl)-urea;

~~or a single stereoisomer, mixture of stereoisomers, or a pharmaceutically acceptable salt, solvate, or a solvate of a pharmaceutically acceptable salt thereof.~~

27. (Currently amended) [[A]] The pharmaceutical formulation of claim wherein the compound is selected from:

(S)-1-[3-(1-Ethanesulfonyl-piperidin-3-yloxy)-5-fluoro-phenyl]-3-(6-methylpyridin-3-yl)-urea;

(S)-1-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-piperidine-1-carboxylic acid methyl ester;

(S)-1-[3-Fluoro-5-(1-methanesulfonyl-piperidin-3-yloxy)-phenyl]-3-pyridin-3-yl-urea;

(R)-3-[3-Fluoro-5-(3-pyridin-3-yl-ureido)-phenoxy]-pyrrolidine-1-sulfonic acid dimethylamide;

(R)-1-{3-Fluoro-5-[1-(ethane-2-sulfonyl)-pyrrolidin-3-yloxy]-phenyl}-3-(6-methyl-pyridin-3-yl)-urea;

(S)-4-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-[(S)-2-methoxymethyl]-pyrrolidine-1-sulfonic acid dimethylamide;

(S)-4-{3-Fluoro-5-[3-(6-methyl-pyridin-3-yl)-ureido]-phenoxy}-[(S)-2-methoxymethyl]-pyrrolidine-1-carboxylic acid methyl ester;

(R)-1-{3-(1-Ethanesulfonyl-[(S)-5-methoxymethyl]-pyrrolidin-3-yloxy)-5-fluoro-phenyl}-3-pyridin-3-yl-urea;

1-[3-Fluoro-5-(R)-(3-oxo-(S)-tetrahydro-pyrrolo[1,2-c]oxazol-6-yloxy)-phenyl]-3-pyridin-3-yl-urea; and

1-[3-Fluoro-5-(R)-(3-oxo-(S)-tetrahydro-pyrrolo[1,2-c]oxazol-6-yloxy)-phenyl]-3-(6-methyl-pyridin-3-yl)-urea;

~~or a single stereoisomer, mixture of stereoisomers, or a pharmaceutically acceptable salt, solvate, or a solvate of a pharmaceutically acceptable salt thereof.~~

28.-55. (Cancelled)

56. (New) The formulation of claim 1 wherein the formulation is suitable for oral or parenteral administration.

57. (New) The formulation of claim 1 wherein the formulation is chosen from pills, tablets, capsules, powders, liquids, suspensions, suppositories, and aerosol forms.

58. (New) The formulation of claim 1 wherein the formulation is a sustained release formulation.
59. (New) The formulation of claim 1 wherein the formulation is a controlled release formulation.
60. (New) The formulation of claim 1 provided in unit dosage form for single dose administration.
61. (New) The formulation of claim 1 wherein the compound of Formula I comprises about 0.005% to 95% of the formulation by weight.
62. (New) The formulation of claim 61 wherein the compound of Formula I comprises about 0.5% to 50% of the formulation by weight.
63. (New) The formulation of claim 1 further comprising an additional active agent.
64. (New) The formulation of claim 63 wherein the additional active agent is chosen from ACE inhibitors, beta blockers, β -adrenergic agonists, phosphodiesterase inhibitors, and diuretics.
65. (New) The formulation of claim 1 further comprising one or more excipient, chosen from mannitol, lactose, starch, dicalcium phosphate, magnesium stearate, sodium saccharine, talcum, cellulose, gum acacia, polyvinylpyrrolidone, sodium crosscarmellose, glucose, gelatin, sucrose, and magnesium carbonate.